EVALUATION OF THE PERCEIVED RISKS OF GENETICALLY MODIFIED CROPS IN EUROPEAN AND AMERICAN CONTEXTS

Kathy Cao

(TC 660H)
Plan II Honors Program
The University of Texas at Austin
Spring 2017

Under the advisement of Dr. Chad Smith and Dr. Debra Hansen

Supervisor:_____ Second Reader:_____

Author: Kathy Cao

Title: Evaluation of perceived risks and benefits of genetically modified crops in European and American contexts

Supervising professors: Dr. Chad Smith and Dr. Debra Hansen

In the past, farmers have utilized many methods such as artificial selection in order to produce a desired crop. In recent times, biotechnology has made its way into agricultural practices and genetically modified (GM) crops became a hot topic issue. GM crops are generally not so different from their conventional counterparts and studies have shown that GM crops do not pose a risk to human health, but Europeans generally feel more antagonistic towards GM crops. This thesis will evaluate where these differences stem from, and why the European Union has chosen to regulate the same technology in such different ways compared to the US. The methods of production, sociocultural opinions, and past regulatory failures in a country such as the madcow disease outbreak have majorly influenced the opinion of a populace on acceptance of a novel food.

Acknowledgements

I would like to express my sincere gratitude for my two wonderful biology professors. I am very thankful for my supervisor Dr. Chad Smith and my second reader Dr. Debra Hansen for providing me their guidance, support, patience throughout the whole year. I have gained very much knowledge from taking their classes and I am very grateful for having them as they have really inspired me in my undergraduate education. I would also like to thank the Plan II program for allowing me to explore beyond the scope of my major and being able to embark on this paper. Finally, I would like to thank friends and family for providing the emotional support that I needed to finish this thesis.

Table of Contents

Part 1 **Introduction**

The prominent marker of human civilization has been the development of agriculture. Through the domestication process, plants have been under artificial selection where farmers have allowed only the plants and animals that have desirable characteristics to reproduce and pass on their genes to subsequent generations. Species have been manipulated over the course of decades for human consumption, lining our grocery stores. Ever since the 1970s, scientists have used DNA technology to directly alter a genome of an organism in order to produce desirable traits. These organisms are labelled as Genetically Modified Organisms (GMOs). Widescale transgenic crop modification has ignited a polarized debate between those who see GMOs as a promising future for sustainable agriculture and for those who see GMOs as a risk to society's well being. Classifying food is commonplace, but certain labels on food come with different cultural perceptions, especially in different parts of the world. For example, organic food has been a modern buzzword that entails ideas about health and well being, while labels like GM have been thought as potentially hazardous. The opinions about GM crops are extremely variable and lead to many disagreements across the world. Historical events that may undermine a country's confidence in risk regulation majorly influence decisions on GM crop approval. Differences in governmental regulation on GM are the major factor in which these disagreements come about and further influence the populace's opinion.

1.1 Purpose of the Paper

This paper seeks to understand the polarized sides of the genetically modified organism debate. It presents how differing ways of regulation and how sociocultural opinions have affected a country's perceived risks of genetically modified crops, specifically in the US and the European Union. GM crop impact on the environment will be assessed along with a comparison to artificially selected crops. The importance of addressing artificially selected plants in this discussion is to show how they are not devoid of risk to the environment either. Traditional forms of agriculture may also exhibit the same potential harm as GM crops. Specific case studies in the methods of production section will exhibit these comparisons. The big reason why the EU and the US regulate similar forms of biotechnology in such dichotomous ways is because of 1) sociocultural aspects 2) recent politics of risk regulation throughout Europe 3) historical events that have undermined their confidence such as the past outbreak of Mad Cow disease in Britain. Later, the paper will exhibit how the two developed countries's risk regulation could possibly influence the future of developing nations and other further implications GM crops may have on the future of effective safety regulation. The rest of this Introduction section will visit the history of GM crops and regulation in the European Union and the United States. It will also visit background of GM crops and the common issues surrounding the risks as well as benefits of GM crop use. Part 2 goes into the biological background and focuses on the methods of production in order to analyze the differences between artificially selected and GM crops. Part 3 will explore the sociocultural factors that possibly influence the debate about GM in general. Part 4 will

define the specific terms in the two countries and will delve into the regulative policies in more depth on GM crops transatlantically. Lastly, Part 5 of the paper will discuss downstream effects of GM regulation on neighboring, developing nations and summarize potential implications of GM use for the future.

1.2 Comparison of the History of Regulation in the US and Europe

In 2010, the United States used GM technology in order to grow more than 80 percent of its soybeans, corn, cotton, etc. The U.S. regulation of biotech was focused on products while the European Union's (EU) regulations are focused on process. As a result, the EU regulates GM much more more stringently.

In the 1980's, the American government started creating regulation over the safe-handling of the possible GM products that would come in later years. In the latter half of the decade, the risk-based system, the Coordinated Framework for the Regulation of Biotechnology (CFRB) was created in order to make an organized collaboration between the Environmental Protection Agency (EPA), United States Department of Agriculture (USDA), and the Food and Drug Administration (FDA). These governmental organizations made sure that the new developed techniques would be safe for human health. Each regulatory body had a distinct job: the USDA checks for effects of GM on other living things in agricultural and non-agricultural settings, the EPA determines if there are any health and environmental effects of GMOs with pest-resistance, and finally, the FDA evaluates possible health problems of consuming GMOs.[1]

So the FDA and the USDA worked together to introduce GMOs. In order to easily import and release the GMOs into the environment, the USDA created Animal and Plant Health Inspection Service (APHIS). With several field tests, GMOs were able to move

[1] EPA

with more ease through states.[2] These procedures helped simplify the process and they were created in order to cover a majority of GM products[3] Later, we will visit the specific cases that were included or excluded from these guidelines.

The European Union (EU) and the United States (US) have regulated biotechnology in very different ways, especially in public health, environmental, and safety. This major difference lies in the differences on management of technological risk.[4] In the late 1960s, regulation was generally more strict in the US than in Europe[5]. In later years, this switched where the EU decided to increase their health, safety, and environmental regulations becoming much more restricting than the US. The EU regulated GM crops in a similar manner to the US in the 1960s strewn with politics, controversy, and often suspicious of industry. Likewise, the US's measures were like how the EU regulated them in the 1970s. The regulation organizations heavily worked together with the industry were extremely supportive of technological innovation.[6]

Significance

In the middle of all the controversies, there is an unclear difference between the scientific-assessed risk of GMO use and the perceived risk as it is influenced by cultural opinion and governmental regulation. Because of these variable opinions and risk evaluations within different countries of GMOs, it leads to issues in import and export of GM crops to other countries. Agriculture markets across the world have very different views of the risk associated with GM crops so this leads to usage or rejection of GMOs

[2] Food and Drug Administration
[3] Vogel
[4] Brickman, Jasanoff and Ilgen
[5] Lynch and Vogel
[6] Eichenwald, Kolata, Peterson

in specific countries. Because of this, rejection of GMO usage in developed countries would stunt the growth of biotechnology to many other developing countries.[7] This would also make a developing country that was potentially expanding their GMO horizons to discontinue because they felt they could lose a major export/import market.[8]

In the light of all this, there are many benefits in the development of crop biotechnology over the long run. If developing and developed countries accept the worldwide use of GMOs, it could potentially improve future agricultural ventures through a healthier environment by reducing the use of pesticides and fertilizers, reducing over irrigation, reducing the use of agricultural land, improving crops by giving them more stress resistant capabilities, and providing more nutrition.[9] Through public negativity against GMOs, it would essentially prevent the beneficial growth of GMOs in the future.

Anti-GM individuals claim that GMO production produces plants with unknown side-effects, allergens, and potential environmental degradation that inflicts “native” populations. It is widely argued that there must be extensive research into the environmental impact of these GM crops. There is concern over the potential risk from the plant’s transformation along with insecticide resistance. Additionally, there is concern over how a novel gene may unintentionally affect other organisms in the environment.

[7] Juma, Calestous or Paarlberg, Robert L.
[8] ‘’
[9] Nuffield Council on Bioethics

Many GMOs differ by a case-by-case basis so it is very difficult to claim anything under the “umbrella term” of GMO. It is important to look into the risks of specific GMO products on the market rather than make general notions about GMOs[10].

Believing that all GMOs are harmful just because of one case, would not offer a very informative and rational decision making process, and limiting the use of GM products until all has been proven safe about them would not do much for the safety improvement because it should be known that these types of technological developments never have zero risk. Traditional agricultural practices (artificially selected) processes, are not zero risk either. Conventional practices are not free of many of the types of risk that are commonly attributed to GMOs[11]. Therefore only allowing zero risk measures in order to approve GM use would stunt any possible benefits or technological improvements.

Even though there is minimal risks when comparing to their conventional counterparts (artificially selected), an American versus a European consumer hold very different views. The European consumer is usually very suspicious of the GM content of food products and the EU regulatory agency has many strict policies implemented, while the US has very lenient ones put into place, and generally the US citizen is very permissive of GM foods in their diet.

[10] Maghari and Ardekani
[11] Jank and Gaugitsch

Part 2 Methods of Production

2.1 Background on biology

This biology introductory section will review general biology concepts so the audience is able to familiarize more of the technical aspects before delving into the methods of production. This is needed in order to explore the concepts with more depth and to understand where does the differences lay between artificially selected and genetically modified crops. Even with all forms of crop improvement, there is evidence that the environmental effects of even traditional practices may also have destabilizing effects on nearby ecosystems. This section is informative for individuals trying to understand where perceived risk stems from. The two groups that support GM and those that are Anti-GM utilize ecological and biological risk assessment arguments in order to influence policy makers, so by understanding the differences between the two techniques, an audience member is able to draw some conclusions about risk. Of course, describing all the new forms of biotechnology methods is beyond the scope of this paper however, it is informative to name some of the more commonly used techniques in producing GM crops

---

2.2 Genetically Modified Techniques

GM crops are created by inserting a gene externally from an foreign source into unrelated species. This has granted an ability to overcome many physiological barriers and to exchange genetic information among all living organisms. The purpose of genetic modification is to create a faster, efficient, and much more precise way to achieve the same results from artificial selection. Additionally, it can be used in order to introduce a new trait to the crop that would not be usually naturally occurring.

These GM crops can have many beneficial traits that improves the overall charactderistics of the plant this includes: extended shelf-life, drought-tolerance, pesticidal/herbicidal resistance, and increased nutritional yield, etc. Many GM crop examples include: soybeans with resistance to Roundup, a weed killer, corn that has an inserted gene with pesticide-resistance, “Golden Rice” which is includes vitamin A in order to fight nutritional deficiency in developing worlds, and even corn made to be free of specific allergens such as gluten[12]. Non-food items can be made from GMO crops through resources such as biofuels, and plant manufactured pharmaceuticals (e.g. tobacco may act as hosts for protein production instead of using the traditional cell culture method for many different diseases. Certain antibodies may use a bioreactor for the specific patient's’ diagnoses)[13] can also be created.

[12] Séralini
[13] Bruce

The important steps involved in genetic engineering are identifying a gene of interest, isolating that gene, inserting that gene into the crop, and then continuing the line down subsequent generations. The techniques for gene modification have majorly improved over the last few decades. Gene modification started with selective breeding, then improved to insertion of genes, and then finally techniques such as CRISPR using direct genome editing.

2.2.1 Genetic Modification: The Process

GM crops can be made because DNA has the same genetic code in all organisms. The sequences along the DNA chain creates genes which are segments of DNA that provide information to assemble specific protein products. These protein products can be enzymes that catalyze reactions in the organism or they can be lead to expression of a specific trait in the crop.

First, in order for geneticists to *identify a gene of interest,* they start by lookin at other potential organisms.The geneticist has to identify the trait they desire the organism to have and must find any other organisms that already contain that gene. Finding a novel gene of interest requires intensive research into that gene as well as luck. *As an example*, if a scientist wanted a gene that improved the nutrient composition of a plant, they would look through many organisms that they believed that produces that specific nutrient, additionally if a scientist wanted a crop to have a gene that allows it to survive in drought conditions, they would most likely look for an organism living in

those persistently hotter conditions. Additionally, this also involves testing in order to find the organism with the most ideal and “worthy” trait.

Secondly, in order to *isolate a gene of interest*, comparative gene analysis must be done in order to locate and decode the specific organisms gene of interest. Whole genome alignment is done with plants that have and do not have the gene to pinpoint the regions of difference[14], and if there are no pre-sequenced genomes are available to perform comparison tests, scientists will use gene knockouts on the plant genome till the characteristic of interest is gone, thus identifying the gene that generates the specific trait.[15] As an example, Monsanto has been trying to develop much more efficient ways to identify a genome of individual seeds. Before studying the genome of plants required one to wait for the seed to germinate and grow to a specific age and then extract a sample from the leaf to analyze its genome, but that was a tedious and time consuming task, so Monsanto designed a way to study directly from the seeds without wasting resources by grinding them completely. The technique is called seed-chipping which takes a tiny sample of a seed and analyzes it with genetic sequencing, and then allows the viable portion of the seed to be once again planted. By doing this, it creates a genetic database for these plants even before they are grown. The technique is called seed-chipping which takes a tiny sample of a seed and analyzes it with genetic sequencing, and then allows the viable portion of the seed to be once again planted. By doing this, it creates a genetic database for these plants even before

[14] Boerboom, C and Owen
[15] Thorneycroft, Sherson, and Smith

they are grown. The significance of this is to allow scientists to easily select and find the plants that have the most “worthy genes” given their phenotype.[16]

Thirdly, in order to insert a gene of interest into the crop, two general methods can be done. Generally, the transgene that encodes the trait of interest should be inserted into the plant cells, along with some “designer genes”. These genes are the as illustrated by this simplified diagram.

Figure 2.2.1A

Simplified representation of a constructed transgene, containing necessary components for successful integration and expression.

The “promoter” region must come along with the transgene in order for it to be correctly expressed, serving as the initiation site. It acts as an ON and OFF switch. Additionally the *transgene* is a gene that produces a desirable trait. (e.g. the Bt transgene for pest-resistance). In order to know if a specific gene of interest has been uptaken by the plant’s genome, the transgene is usually attached to a marker gene before insertion. The “marker” sequence is placed into the plant to act as a barcode and to help identify the plant tissues that have uptook the transgene successfully. These marker genes also encode proteins that give either herbicide resistance. The plants that have properly uptaken the marker gene will survive once grown on a medium that has the herbicide. Lastly, the “termination” sequence specifies the end of translation or transcription.

[16] Boyle

There are two main methods that are used to transfer foreign genes into plants. The first one involves the use of a plant pathogen called *Agrobacterium tumefaciens*. This bacterium has a plasmid, a, small circular strand of DNA, that contains tumor inducing genes (T-DNA), and other genes that help the T DNA incorporate into the host's genome. For genetic modification purposes, this bacterium must be made harmless so it does not cause sickness in the plant. The plant is put under electric shock or heat stress in order to make it more susceptible to insertion of the transgene. The plant is naturally susceptible to the bacteria, so scientists can properly insert new DNA into the plant's genome.[17]

The second common method is using a "gene gun", (also called the biolistic microprojectile particle delivery system) which fires metal particles (usually gold or tungsten) coated with pieces of the foreign DNA into the plant tissues. Gold is used because it is dense and biocompatible. A genetic marker is also inserted with the metal particle in order to indicate that the DNA incorporated successfully. These particles bypass through the cell wall and incorporate into the nucleus where the plant's DNA is located.[18] The cells are grown in a tissue culture and are bombarded with the metal particles with the gene.The cells that uptook the DNA are selected for from the media and then propagated. When the particle is inside the nucleus, the gene leaves the gold particle to be inserted into the chromosome.[19]

[17] Kharkwal, M. C., & Roy, D
[18] Slater, Adrian; Scott, Nigel; Fowler, Mark
[19] Barry, M., Andersson, H., & Singh, R.

Using *Agrobacterium tumefaciens* to insert genes is preferred because it gives higher probability that the transgene will be incorporated and easily tracked. Both methods give fairly random results. This is because it is hard to control where the positional incorporation of DNA may occur. DNA could potentially incorporate into silent regions of the genome or it may incorporate close to or far from important transcriptional activating elements. Which may result in activation or lack thereof of transgenes, so a scientist must do multiple checks to see if the plant has assumed the foreign gene. [20] Once it has been seen that the plant has the gene of interest, it can be passed to any progenitors. It is not always guaranteed that the offspring generation will also have the proper genes. It is possible that plants may suffer myriad side effects if the gene does not locate in the proper place on the genome.[21]

There are difficulties in identifying and locating genes. Researchers have limited knowledge on the agriculturally significant genes such as increased plant hardiness, increased yield, or environmental tolerance. Identifying a single gene involved with a trait is not enough for this step because researchers must understand how a gene could be regulated, what other effects it might have on the plant, and how it interacts epistatically with other genes in the regulation pathway. Genetic modification is used to transfer genes that produce traits such as insecticide, but many genes do not function independently from one another. Additionally, proteins also work in a very dependent

[20] Beilmann, A., K. Albrecht, S. Shultze, G. Wanner, and U. M. Pfitzner.
[21] Boyle

and dynamic system. This means that one gene inserted may not just result in expression of one trait.

Additionally, one of the most revolutionary gene editing tools was invented in 2014. Clustered regularly interspaced short palindromic repeats (CRISPR), has been gaining popularity in the GM world. CRISPR/CAS9 allows scientists to accurately change existing sequences, add sequences, and delete existing sequences in the genome. Genetic engineering mostly relies on transgenes introduced from different species, but with CRISPR, the genome can be just directly edited. With more and more accurate forms of gene editing, it would make studying gene products easier. This can reduce any perceived risk about genes coming from a "foreign source".[22] But this may result in stricter regulation on what defines a GMO and if directly editing genome can avoid unwanted protein products. These recent developments may radically modify how governments define and regulate genetic engineering in agriculture for the future.

Finally, *propagation of the* GM crop requires the genotype of the crop to be intensively tested such that the modification was correct. After a genetic trait has been successfully inserted into an organism's genome, the modified organism must then be able to grow and replicate with its newly inserted gene. They also must do intensive testing such that these plants have the most ideal traits that are relatively consistent throughout the generations. They also must test these plants through many different conditions to make sure that these plants will not act harmfully given different environment conditions. Optimal conditions to generate the highest yield potential is

[22] Neb Biolabs

tested such that for the future these GM seeds when sold in the marketplace will come with the proper instructions on how to ideally grow them.

In summary, genetic modification requires multiple steps in order to properly produce the ideal plant. These steps include identifying candidate genes, insertion of the gene, assessment of incorporation of the gene, and propagation of the plant.

2.2.2 Assessing the cons of genetic modification on crops

For the GM debate, it is difficult to see where scientific evidence ends and speculation begins. This section will delve into assessing the scientific arguments anti-GM groups present. Additionally, these scientifically based arguments are what policy makers use in order to justify their regulatory decisions on potential ecological and food safety risks.

There are difficulties in identifying and locating genes for gene scientists. Researchers do not have a complete understand of all the genes associated with specific characteristics. Having limited knowledge on the genes on agricultural-significant traits like increased plant hardiness, increased yield,or even environmental tolerance creates difficulty. Identifying a single gene involved with a trait is not enough for this step because researchers must understand how a gene could be regulated, what other effects it might have on the plant, and how it interacts epistatically with other genes in the regulation pathway. Genetic modification is used to transfer genes that produce traits such as insecticide, but many genes do not function

independently from one another. The human genome operates in a very complex system of dependent genes. Additionally, proteins also work in a very dependent and dynamic system. This means that one gene inserted may not just result in expression of one trait. Further improvement on gene optimization and studying the profiling of genes with more detail should be done in order to reduce any difficulties that arise with epistatic gene interactions.[23]

Under one argument, if GM crops were to cross-breed with wild relatives or with conventional crops, the foreign transgenes could “contaminate” the natural ecosystem. They are able to cross-breed because GM crops are not that genetically different from conventional crops (e.g. teosinte with Bt-corn or non-Bt crops with Bt-corn). It would be extremely difficult to eliminate a dangerous GM crop if it had already spread into the environment. Additionally, this contamination would pose problems for the international marketplace and certified producers of organic produce. Overseas countries have different standards on the regulation of GM crops and different opinions about their safety. If there are disagreements between two trading partners then the acceptance of produce to another country may be deemed unmarketable.

Another argument is there may be harmful ecological effects of GM crops on nontarget organisms. GM Crops that contain herbicides or insecticides, are believed to cause adverse impacts on non target organisms, but even after much intensive testing it is reported that there is lack of impact on nontarget organisms.[24][25][26]. Studies were done

[23] Phillips
[24] Naranjo
[25] Yaqoob et al.
[26] Lazebnik, J., Arpaia, S., Baldacchino, F. et al.

and differences were compared with conventional and GM techniques for pesticide mitigation. In some studies, it showed evidence that the GM crops with these herbicides and insecticides were are much safer to nontarget organisms than using traditional pesticides on pests targeted by the GM crops.[27] Even with these studies, regulating agencies must still find effective strategies to manage, identify, and mitigate any key risks of concern when there is potential ecological harm.

Biotechnology critics have been concerned about food allergens in response to proteins developed in GM crops leading to many arguments over regulatory proposals.[28] In 2000, there was an uproar on media after a Taco Bell customer went into anaphylactic shock after eating “starlink-corn contaminated” tacos. Starlink corn produces a pesticide protein called Cry9C. The public believed was concerned with this contamination of Starlink corn with non-GM corn, but the FDA concluded that there was no direct link between the Cry9C protein and the allergic reaction. Additionally, many individuals also ate the same Starlink-contaminated tacos, and there were no additional reports after that. In another study, it showed how the Cry9C protein reaches the gut of the lepidoptera and causes the protein to release toxic contents[29]. The mechanism for the release of the toxin will only occur if there is a matching protein receptor. This receptor is only present in the lining the larval insect, so the toxin only impact insects species-specifically.[30]

[27] Naranjo
[28] Royal Society
[29] Roh JY, Choi JY, Li MS, Jin BR, Je YH.
[30] Niederhuber

An additional study also claimed that technology used for making GMO crops does not necessarily make us more vulnerable than conventional breeding. There is no evidence that GMOs are any more or less allergy-inducing than nonGMO crops.[31] Host and environmental factors are what determine the intensity of an allergic reaction. Under the international statutes for food safety listed under the Joint FAO/WHO Expert Committee on Food Additives (JECFA), before any modified food product is marketable, the structure of the gene product is compared with all previously studied allergens. Possible allergenicity is further studied with many scientific experiments. Even after the product goes live, consumers are randomly sampled in order to guarantee there were no previously unknown allergenicity that go undetected.[32]

In contrast, by improving GM technology scientists could actually be able to produce GM crops that are rid of common allergens. For example, with the large population of individuals that are allergic to soybeans, there are as many as 15 protein products naturally from soybeans that cause allergic reactions in consumers. Creating hypoallergenic soybeans would be very beneficial since there is just such a large market that utilized soy products. These developing hypoallergenic versions have the potential to mitigate adverse reactions (anaphylactic shock) in sensitive people.[33]

Another argument anti-GM groups bring up is the fact that GM crops creates superweeds. “Superweeds” are any plants that generally have pesticide resistant, as in that allow them to survive any spray on pesticide application. These plants are generally

[31] Xu
[32] JEFCA
[33] Burks et al.

"weed"-like because they dominate other versions of the plant for resources. After the weaker plants are eliminated, only the most hardy survive and then are able to continuously propagate giving their resistant genes to their offspring. Without properly rotating crops around yearly, resistance cannot be detered. Bt- corn is resistant to herbicides, so this allowed many farmers to use them generously, but after utilizing this GM crop for many decades, the superweed proliferated and was found in other farmers fields thereby reducing their crop-yield. Despite this, resistance in pesticide use or herbicide use is a problem that all farmers have not dependent if they plant GM or nonGM crops. There have been already many superweeds that have appeared over the decades. Traditionally, farmers used simple techniques in order to get rid of weeds, this includes conventional tilling, ploughing, and spray-on pesticides. This biotechnology created GM crops that allowed farmers to depend solely on one using spray on pesticides. But, using the same pesticide will select for superweeds in the long run.

By using genes extracted from viruses or bacteria, there is a concern that these foreign genes might expose the consumer to an negative reaction. As an example, the Bt-soy has the CaMV promoter extracted from the Cauliflower-mosaic Virus. One study that claimed genes could be absorbed into the blood stream and can be incorporated into the DNA of the consumer[34]. Humans and plants may have some similar genes that we share, but this study had additionally more reviews that claimed it was cherry picking for data.[35] Based on common knowledge of digestion, macromolecules (DNA, fats, proteins, and carbohydrates) are broken down into monomers and intercellular junctions

[34] Ho & Cummins
[35] Bawa. & Anilakumar

allow them to be channeled through the digestive tract and into the blood. The blood is unable to carry large pieces of foreign macromolecules as this could potentially lead to a negative immune response.[36] There only have been limited studies and this promoter gene has been implemented in a majority of GM crops that are already on the market. It does not seem to reveal any health risks in the populace.

In summary, GM crops have generated many debates over any risk assessments for the environment and to human health. The widespread debate looms around biotechnology's balance between planting high quality crops, while protecting environmental and human health. The arguments brought up by anti GM groups and proGM groups have offered very conflicting ideas on the benefits as well as the risks to society. The fears that individuals have do have a scientific basing, but there is lack of evidence to prove any of the fears true. Even served as a case-by-case basis no significant reportings have been made.

By understanding the methods of production of the two techniques and then comparing and contrasting their general risk assessments, one can further understand how these arguments may be used to regulate policy which will be visited in the next section. These scientifically based risks offer a window into the analysis of how they are perceived to be. There is generally a difficulty in drawing any conclusions from their actual harm, but the perceived risks have been studied such that we can draw conclusions on how the populace may feel.

[36] Katirae

2.3 Artificially Selected Techniques

In order to understand the perceived risks of GM crops, a comparison of risk in traditional agricultural techniques should also be studied.

For thousands of years, humans have been altering the genetic composition of food stocks in order to improve crops. Farmers have utilized artificial selection in order to manipulate the specific features of their crops over many decades of selective breeding. By only allowing the crops with desirable characteristics to reproduce, it causes the evolution of that species. Artificial selection improves lives of farmers because they choose desirable characteristics of their crops like disease resistance and abundant fruit which then helps them by reducing the amount of work they have to put in to get the same amount of yield.

During the First Agricultural Revolution, in 10,000 BC, domestication of crops began with many different crops such as barley, dates, wheat, lentils, peas, beans, olives. Domestication of these crops had increased the food supply, which helped support human population growth. Seeds from any wild plants were actively collected, planted and cultivated. When the crops were harvested, the seeds from ideal crops were chosen for the next growing season. Farmers identified many types of genetic variants and compared their yields once cultivated. Inferior crops that did not perform so well were removed from the stocks.

The many traits that farmers had selected for are very similar to the ones that farmers select for today. These desired characteristics may include: higher yield, even

growth, even germination, time of flowering, hardiness (drought and disease tolerance), ability to fight off any infection and insects, and high quality products. Farmers could only rely on natural variation and natural genetic mutations as they did not have the genetic analysis tools like in modern day to identify specific genes on loci.

Much of the purchasable produce in the market today is by far from “natural”. Through artificial selection, the best and sweetest fruits have been selected resulting in looking nothing like their ancestors. As an example, the corn that many people consume looked nothing like its ancestor, teosinte. Teosinte phenotypically is very different but genetically it is related to modern corn.

Figure 2.3A[37]

Thousands of years of selective breeding of maize uncovered by archaeologists

In the case of corn, the farmers bred and planted the teosinte that had sweeter, larger, and more number of kernels. Through repetitive selection in successive generations, these desirable attributes were given to their offspring. This resulted in a population of

[37]Photo by Robert S. Peabody Museum of Archaeology, Phillips Academy, Andover, Massachusetts.

crops that have abundant fruit production in comparison to their wild counterpart, and as exhibited in the Figure 2.3A.

2.3.1 The downsides of artificial selection

There are many problems that are associated with artificial selection such as detrimental ecological effects as well as a decrease in genetic diversity. When continuously propagating or breeding a crop with similar traits with each other, there may be an increased susceptibility to disease because it lessens the amount of variation that exists in a gene pool. The individuals in a gene pool are too alike so there is less chance that there is a crop that will survive a pathogen attack.

Additionally, artificially selected plants may not necessarily have the same beneficial traits as GM crops. They will potentially need the farmer to utilize much more fertilizers, insecticide, and his own time in order to compensate for more yield. This in turn may damage the environment through fertilizer runoff into nearby ecosystems. Fertilizer runoff can lead to devastating environmental effects such as eutrophication, algal blooms, and then dead zones (causing oxygen depletion in marine ecosystems).[38]

There is an argument that superbugs can be created with GM crops. Superbugs are an organism with a resistance to a pesticide. These pests are created by repetitive administration of a pesticide where the ones with resistance survive. Down subsequent generations superbugs are then able to reproduce giving the whole population immunity to the pesticide. This fails to address the other side of the issue with conventional farming practices. With just conventional farming practices, one still uses pesticides in

[38] David W. Schindler; John R. Vallentyne

some form to rid of a pest. Without the use of GM crops that have a gene for herbicide, techniques such as tilling and ploughing must be done to rid of weeds. These are labor intensive and induces CO2 emission from the soil.[39] In comparison, pests are either eliminated with a gene producing pesticide resistance or a farmer is physically spraying pesticides on the plant to eliminate pests. Over time, insect populations can become more and more resistant to the pesticide. Both ways can produce superbugs with pesticidal resistance.[40] Additionally, the EPA has created guidelines in order to regulate superbugs effectively for GM crops. By planting conventional crops and GM crops next to each other or rotating on a yearly basis, ensures that there are a sufficient number of susceptible insects. Susceptible insects may take refuge on conventional crops (that do not have Bt-resistance) and mate with any resistant insects.[41]

Both techniques may potentially cause unintended effects by altering a population's gene pool.[42] Both techniques require adding genetic variation to the current pool and then weeding out those that have undesirable traits or those that do not contain the traits of interest. After an evaluation of the USDA in 2002, the committee proposed GM crop improvement does not not pose any more risk than with traditional crop improvement techniques,[43] but they also concluded that specific traits introduced by both techniques may pose unique risks served as a case by case basis. Risk regulation for GM crops have much higher environmental standards than with

[39] Reicosky
[40] Gilbert
[41] EPA: Insect Resistance Management
[42] Lukaszewski
[43] National Research Council; Environmental Effects of Transgenic Plants: The Scope and Adequacy of Regulation

conventional crop improvement.[44] In retrospect, there needs to be a reevaluation for studying the environmental effects of traditionally improved crops, but regulating this would have much tedious work and would make the lives of farmers much more restricted.[45]

In summary, in the time period where conventional plant breeding was practiced, farmers were not concerned with issues like nontarget effects and gene flow. Government agencies are faced with a difficult issue on the regulation of transgenic plants on the environment and must evaluate with more stringency than the rules used to regulate the impacts of other traditional forms of farming techniques. By understanding the risks set by traditional (artificially-selective) crop improvement techniques, one can compare these to GM techniques and then understand the possible ideas that a country may account for when approving certain GM crops. These certain ideas set the background knowledge for how regulation may occur, and these comparisons generally may set the attitudes on why individuals perceive GM crop techniques to be harmful or beneficial.

[44] National Research Council; Comparison of environmental assessment of transgenic plants with assessment of other agricultural technologies
[45] USDA: Environmental Effects of Transgenic Plants: The Scope and Adequacy of Regulation.

Part 3 Sociocultural effects on the perceived risks of GM

The average person generally does not have much knowledge about genetically modified organisms, and so if an individual was shown a label about them, they would usually be averse to them. Individuals may associate these genetically altered plants as a novelty, and culturally there is a psychological tendency to want “naturalness” in food, but artificially selected plants are by far from their natural counterparts (e.g. teosinte). Dr. Jayson Lusk, a food agriculturalist from OSU, believes that perceived riskiness depends on familiarity and control over the subject. Things that are novel are generally perceived as riskier.[46]

American and European journalists have suggested differences in perceived riskiness in their own countries might be caused by certain cultural foundations. Europeans hold a deep belief of “naturalness” in traditional food and are generally hostile toward “food-fiddling of any kind...”. When looking at the American daily cuisine, it is strewn with larger amounts of processed and fast foods.[47] It is recorded that Americans use more preservatives and processing food methods compared to most countries in the world. There are around 250,000 fast food establishments in the United States while there is only around 10,000 in all the European states combined.[48] The

[46] Ferdman
[47] Swardson
[48] Statista

United States is also generally open to many new food products given the growing, competitive industries on the marketplace, while European consumers generally place a higher value on local and fresh varieties and stay much more traditional on food consumption spectrum.[4950]

This competition in the food industry can be observed in America where food additives that are “generally recognized as safe”. They can be easily added into consumption goods without any government oversight. (This is done through a law established by the FDA that had the original intention to allow incorporation of simple additives like salt without tedious paperwork on safety analysis). Food companies have used this loophole in order to get their products in the grocery stores quicker, thereby explaining this novel food acceptance.[51] Now looking toward the European Union, all ingredients incorporated in consumable goods goes through an extensive and stringent risk assessment.[52]

Differences in attitudes can also be related to the geography. Europeans live in closer to areas of agricultural production than in America and associate GMs as a contamination to their “natural farmlands”. Journalist propose that being “out of sight is out of mind”. The “countryside by genetically modified crops... scarcely occurs to Americans, whose landmass is big enough to separate its agricultural heartland from rural playgrounds...”[53]. Despite this, Europeans would then be closer to pesticide and herbicide spraying which also are a health and environmental hazard, but opposition to

[49] Greenberg
[50]
[51] Quinn & Young
[52] Vogel
[53] Ottawa

their use has been muted. European agriculture has been dominated by small, family farms using conventional methods of production, much of European agricultural production is dependent on heavy use of herbicides and pesticides.[54]

In the late 1990s, the European food industry announced plans to begin the voluntary labeling of products in order to calm consumer fears about unknown ingredients.[55] Other food companies and retailers across Britain adopted the same terms to stock their grocery stores.[56] Even Prince Charles believed that there could be long term consequences on the environment if we kept “playing in the realms of god”[57] Additionally, British press journalists criticized Monsanto and expressed many negative opinions.

Europe, in the past, has carried anti-American sentiments spurring the media due to many reasons. The first reason was Monsanto, the American multinational agricultural biotechnology corporation, was the first company to push GM crops to Europe. The company also failed to label them which caused much controversy and unrest among European consumers. The Europeans had claimed “they were being deprived of their freedom of choice.” and were “angered when they "tried to educate them about the value of GE crops”[58] The second reason was because Monsanto had made an investment in many seed companies, suspicion arose when rumors about a “terminator transgene” would prevent crops from producing fertile seeds which would

[54] Diahanna & Vogel
[55] MacKenzie
[56] Greenberg
[57] Randall
[58] Roseboro

force farmers to buy new seeds harvest. They all believed that Monsanto had plans to monopolize and control the European continent's food supply.

How the citizens feel

Public concern about the dangers of GM products for Europeans were on the rise from the 1980s. Many individuals created cabinet-level committees that delved into the the effects of "Frankenfoods" as portrayed by the UK media.[59] Under a survey asking if a citizen believed if GM foods are a hazard, 85% from Sweden, 57% from Germany, 48% from Netherlands, 49% from the United Kingdom believed GM foods were a hazard. Additionally 64% claimed they would not eat GM foods. In retrospect, 80% of Americans believed GM foods were safe to eat, and 75% of them would eat them.[6061]

Even though that majority of Americans would be willing to eat GM crops, they still would like to know what is in their foods. Regardless of what political party they are in, Americans favor the "right to know". In four different polls, around 90% of Americans would like their foods to be labelled.[62] Americans felt that they should have a choice in regards to the products that they consume and purchase. This should include knowing how their food was produced even if it has no consequence or is different than its traditional counterpart. Surprisingly, proGM groups claim that by labelling GM products, it can also be a positive thing because this can show how these products are no different than their conventional counterparts. "If the industry really believes that GMO

[59] Urry & Parker
[60] Hoban
[61] Ayers
[62] Center for Food Safety

food is fine ...then slap a smiley-faced DNA helix on the package and promote ... GMO is in most of your breakfast cereals, soups, cooking oil, milk and frozen foods"[63]. In order to prove to individuals that GMs are safe, the populace would just need to continue consuming GM products as they have been. A country may become desensitized as long as we have these labels and as long as customers continue to consume them. GM labels could slowly change over time to become more accepted.

Many also criticize that the new US federal law would possibly affect poorer Americans because many companies would be losing profits from many consumers avoiding GM products which then may cause new increased food prices.

Despite these cultural differences, it is still unclear as to why Europeans would believe something that is a GM is hazardous when they live near conventional crops that require potential hazardous methods of production. Perceived risks of GM foods stem off of government regulation. Further analysis on why the citizens believe that GM foods are hazardous will explained by delving into the policy side.

[63] Caplan

Part 4 Governmental Regulation of GM in the US and Europe

The intention of this section is to observe how there is a dichotomous regulation of GM in two general areas, the US and Europe. Europe will be studied with regards to the EU and its member states. Later, an analysis on the reasons for this difference will also be studied. These two areas were selected because they have similar historical backgrounds, culturally similar, and are both economically developed.

This analysis will also visit the historical context and the framework of the government that may have caused citizens to perceive risk a certain way.

This analysis will also include developing countries because it shows an important implication for the downstream effects and possible world wide views on the GM debate in terms of safety. There are certain risks associated with GMO use that affect the political, social, and economic sectors of a country.

Introduction: Regulation In Two Worlds

Regulations in the US are generally much more relaxed and usually focus mostly on the final product rather than the process. In comparison, the EU focuses more on the process approach. As an example, under the products approach, the regulation is solely based on the traits of the final product, regardless of what process was used to make it. The process approach focuses on the assumption that the products that are generated

are extremely different or potentially more risky than conventional counterparts. Process approaches require much more regulation along each step of the way.[64] Despite the differences in approaches, both places have similar goals: to ensure that there is enough evidence that says these foods are safe enough for consumption.

Europe was faced with a shaky start on regulation of health and food safety after World War II. Even though many European countries tried to regulate food resources together, there were many food crises along with the 1990s mad-cow disease outbreak. All these regulatory failures led to the creation of more stringent policies in the late 1990s to early 2000's.[65]

The regulation of GM food is not just involved with protecting consumers from contaminated foods. There are many bodies that influence policies and these groups include: producers (the farmer), consumers, and NGOs (nongovernmental organizations), biotechnology industries, and of course the government. Between the groups, there are generally conflicting interests and the government must utilize scientific data in order to assess impacts GMOs may have. Even though the US and the EU regulate biotechnology in different ways, they still use the same scientific backing in order to get the approval process started.

[64] Breyer et al.
[65] European Commission. (2007). 50 years of Food Safety in the European Union.

4.1 Guidelines for Labelling and the Definitions

US regulation

"Genetic engineering", is a technique in which an organism's genome is altered in such a way that does not occur naturally.[66] It encompasses the technique in which one manipulates an organism's genes by introducing, eliminating, or rearranging in order to get a favored gene result.

The FDA requires that food companies label their GM foods as GMO as long as the info does not mislead the consumer. The FDA says the word "genetic modification" has a large range of meanings it could mean anything the alteration of an organism's traits to artificially selecting it. Genetic modification can include traditional hybridizing techniques, but it could apply to any cultivated food because most of the food that we have today is far removed from its ancestors. But on an actual product, the individual may list that the product is "not genetically modified through the use of modern biotechnology"[67]. This will be the definition that is widely used today.

In order to properly approve a nonGMO food, companies must go through strict documentation on their handling procedures. First, the company must observe the agricultural techniques; how the producer grows, harvests, and distributes the crop. At the distribution step, they must make sure the crops are separated from GM crops in

[66] World Health Organization
[67] FDA

order to avoid any complaints about contamination. Finally, the companies must have a detail record attesting to all ingredients added in the distribution chain.

If they desire to have a certified organic food label, then more requirements must be met. First, they must fill out paperwork involved with the USDA agricultural marketing service that administers the National Organic program. The product must be not handled with anything non-organic, and finally the company should have have multiple tests done in order to confirm that the product is actually organic.

This definition becomes more convoluted as the FDA claims that the food produced using genetically engineered food processing aids like GM enzymes, and the meat, milk, and egg products extracted from animals that have eaten GM feed or have used GM vaccines, are not considered to be genetically engineered foods. The regulation of GM crops is very complicated by global trade in food and differences among regulation in other countries has created much issues between groups.

In order to approve GM crops for consumption in the US, it must go through the different parts of the Coordinated Framework. The agencies under the Coordinated Framework are the Environmental Protection Agency (EPA), Food and Drug Administration (FDA), and the U.S. Department of Agriculture (USDA). GM crops must go through many tests on the health safety and the nutritional value of it all. As a comparison no other types of crops --organic or conventional-- goes through the same extensive regulatory approvals as GM crops. The review process requires the USDA to evaluate possible effects of GMOs on other living organisms in agricultural and non-agricultural settings. They essentially perform a review on GMOs that proves they

are safe to grow in any environment. The EPA evaluates any GM crops with pest or herbicide resistance. This includes selective and nonselective herbicides that control many different species of weeds. The FDA evaluates any significant health problems posed by GMs with consumption. The review process and scientific data used to make all these claims are later published and made available to the public. If there are any following up studies that show any harmful effects of pre approved GM crops, then they are submitted to the Coordinated Framework in order to be reviewed. Most of the studies that the FDA has come in contact with has questioned safety of GMOs, but none of them have been found scientifically valid, or most of them have been inconclusive.

Similar policies that are used in the approval process for conventional crops are the same for GM. During the Reagan administration in 1986, the federal government wrote a document that created the Coordinated Framework. Under this document, it claimed that crops that were genetically engineered are not significantly different from conventional crops. This comparison was made under a environmental, human health, and nutritional value comparison. Therefore the government had concluded there was no need for further legislation in order to approve GM crops. This meant that for the regulatory agencies, similar processes for conventional crops are used in order to approve and evaluate GM crops. Regulation is aimed at the final product rather than the process in which the crop was created.[68]

[68] EPA

In 2015, a total of 64 countries have required labelling for GM products that entered the marketplace[69]. Under these labelling laws, there is discrepancy in the threshold content of GM between different countries, and these different thresholds of approval have conflicting labelling laws overseas. GM foods are classified, by the FDA, as “generally safe” and they did not require any special labels for market approval before 2016. A central debate still continued around proposals regarding the mandatory labeling of GM foods. In 2016, under President Obama, the Public Law 114-214 was passed in order to regulate GMO food labelling.[70] Food packages lining the grocery store would carry some sort of text labels or a scannable code to indicate the GM content of the product.[71] The Federal Food, Drug, and Cosmetic Act or FDA regulations has provided the guidance to assist the producers and have required any GM product to be labeled truthfully.[72] Product safety is evaluated with by checking if the GM crop produces allergens or toxins, if it is nutritionally similar to its traditional counterpart, and if it does not affect nontarget organisms.

The first step in the process requires companies to go through a consultation in order to determine whether their GM product needs premarket approval. There have been around 200 consultations that have shown to be exempt from premarket approval [73]. Many companies are able to have exemptions just by proving that their crop or food product is substantially equivalent to a pre-existing food product on the market. In this

[69] JLI Campaign
[70] Public Law 114-214
[71] Strom
[72] (FDA 2016)
[73] Strom

case, “substantially equivalent” means compositionally, nutritionally, or as safe as a traditional counterpart.[74] This part of the approval process is the starting point for the safety assessment. As an example, for Syngenta’s Bt-corn, the company had submitted data that compares their genetically engineered corn with conventional corn. Their scientific data showed that they had similar amounts of nutritional content and were compositionally similar (in the form of oils, starches, and protein content). Their study had proved that the crops were not significantly different, and this was sufficient for approval onto the marketplace.

The USDA evaluates if the crop can be safely grown in the environment. This is evaluated by checking if the crop harmfully affects nontarget organisms. The USDA evaluates if the GM crop should be under a regulated or unregulated status. Generally, regulated plants are required to be under strict surveillance on the frequency and location of planting.[75] Sygenta’s corn gained nonregulated status the company demonstrated stability in its pesticide protein (through passing of genes in subsequent generations), it did not have abnormal crop yields, and finally it was not a weed.

The EPA regulates GM crops with pesticides or herbicides and assesses how these crops many potentially affect the environment and human health[76]. Syngenta applied their Bt-corn under the EPA and provided scientific data on how the the pesticide protein, when consumed, did not cause dangerous immuno-responses on lab rodents[77]. They recognized that there was a possibility of insect resistance with Bt-corn,

[74] International Food Safety Network
[75] Library of Congress
[76] EPA
[77] Tutelyan

so the EPA required the conventional corn species to be grown alongside Bt-corn or rotated on a yearly basis. Bt-corn also had to be monitored such that it produced enough of insecticide to eliminate pests. [78]

With all this information, the EPA deemed it was sufficient for Syngenta's Bt-corn to be consumed and could be properly regulated in the environment.

European regulation

The European Union has a framework similar to the US but has more guidelines in order to be approved. The European Food and Safety Authority, EFSA, makes an assessment of any potential risks that GM products may have to human or environmental health. Their role is to provide scientific data to the regulatory bodies. This includes individual EU member states and the European Commission. Both of these regulators determine which GM products are able to enter the marketplace. The GMO Panel under the EFSA was created in order to accept all applications from individuals desiring approval of a GM crop or organism. Applicants must perform many different tests on their GM product in order to ensure proper human and environmental safety, and all of this information may be accessed by the public.

Under the EFSA, additional definitions for specific regulations such as in order for a GM product to be approved they must go through extensive labelling. Their "Traceability Clause" requires all agencies involved with producing the GM product to provide detailed information (such as location of supply, unique identifiers, and what

[78] EPA

parts of the product is GM or GM free) all the way down the supply chain. This information must be passed along everyone involved in the chain including the customer purchasing the product with a label. The EFSA also has different regulations on “GM stacks”. GM stacks are the plants that have more than one genetic modification, and the EU uses the most stringent guidelines in order to assess safety of these multiple transgene crops. These additional labels reveal the sheer level of detail that goes under scientific review.[79]

When a biotech company submits a review for approval of a GM crop, the EFSA goes through the scientific risk assessment. This centralized regulation agency evaluates GM crops effect on human health and any environmental risks. The company must provide a detailed risk assessment of how the GM crop is deemed equivalent to a conventional counterpart, how it poses no danger to human health, and how the spread of the transgene into the environment is minimal. Later this data is sent to the EC and member states to be evaluated and voted on. Following approval, GM foods on the market must adhere to labeling guidelines. Post-market approval requires that food products must not contain more than .9% GM-based materials otherwise it must be labeled as genetically modified.[80]

In summary, the US requires companies to send in an application to the Coordinated Framework: EPA, USDA, and the FDA to assess the safety of the product before being able to go to grocery stores. The EU requires all GM foods be regulated under the EFSA, who evaluates human and environmental risks, and then the GM

[79] EFSA
[80] Davison

product is voted for by the European Commission and individual member states in order to be approved.

4.2 EU and US regulation with historical context

The regulation of GM started in the 1970's similarly in both regions, but diverged with a set number of reasons. American legislation in the past was faced with two questions: did the US government already have enough authority to regulate biotechnology and if they should regulate the process or the products of GM technology. As referenced earlier, the US took on the approach that there was nothing unique about GM crops versus conventional counterparts.

The European Union started intensively regulating GM technolog in the 80s. The EU's Biotechnology Steering Committee was created and established the Biotechnology Regulations Inter-service Committee (BRIC). This regulatory agency was composed of Directorate Generals that were under the European Commission to control GM products. In comparison with the EPA, the Directorate General of the Commision on the Environment, Consumer Protection, and Nuclear Safety (DG XI) had more direct power in the regulation of GM and chose a more "process-directed approach" unlike the US which decided to take a product-directed approach. Under the EFSA and of the EU's framework for GM regulation, the member states have their say in deciding if they desire a GM crop to be distributed or grown in their territory. [81]

[81] EFSA

In the 1990s, after all the extensive regulations were created, they were put to the test. The EU's clause on distribution of GM foods made it very difficult for the GM crops like GM-canola to be accepted by all member states. The United Kingdom had approved the canola plant while many some countries (Austria, Denmark, and Norway) feared contamination of their conventional crops.[82] The crop was eventually accepted and was readily labeled as GMO. This is important because larger member states usually have bigger influence. If smaller member states disagree with more influential member states that rejected a product, it would be difficult on their economy if they were to accept it because they would have to go through extensive regulation measures in order to prove there has been no contamination of GM crops in their conventional crop lands. It would be very difficult on their economy so many member states avoid these measures and often choose to follow the influential member state's decisions.

Additionally, Switzerland desired to market genetically engineered corn and gained approval from the European Commision. Many of the member states had openly protested and the European Parliament stepped up to question the EC's decision. They desired the EC to ensure the safety of the product with additional testing. Eventually this crop was also accepted, but this instigated the EU to revise their regulation policies for the future to be much more stringent.

[82]Lynch & Vogel

Considering overseas markets, the United States also tried to commercialize their GM soybean and corn to Europe. Their corn was approved to be imported in the EU but initially it was because the US claimed it was nonGMO, when it actually was GM.[83] Even though the EU had approved the import, a trade agency called the Euro-Commerce requested that the US must prove that their GM crops were distributed separately from their conventional[84].The US felt that this was a violation of world trade laws that were already put into place. All this created high amounts of controversy on European media, and public protests ensued. In response, the EU and the Member states were forced to create more stringent assessments especially on aftermarket and commercial release. This all had furthered the development of rigorous applications of the Precautionary Principle. The Precautionary Principle says that if a new product or process has unknown effects or any effects that are debated, then the introduction of this new product must be not be accepted.[85]

In summary, the EU have much stricter labeling and regulations while the US labels with leniency. The US mostly focuses on the final product while the EU goes into the very details of the process. Even though these regulating bodies have these differences they both share a common goal to ensure to the customer that there is safety under their standards.

---

83 “

84 Alison Maitland, "European News Digest: Call for Ban on Biotech Beans," *Financial Times*, October 8, 1996: 2.

85 Andrew Jordan and Timothy ORiordan, "The Precautionary Principle in UK Environmental Law and Policy", p. 70. 71.

Analysis on risk regulation in two worlds

The EU is a regulatory state for regulating policy in the majority of Europe. The many parts of the EU and its member states play major roles in improving the representation of smaller NGO groups. The division of power in the EU allows for more political participation for the citizens. Ever since the 1970s, under environmental policy, the individual representation of its citizens are very strong given active public participation. In recent times, the EU has gone major steps in improving consumer protections due to the past regulatory failures that threatened the food supply. In comparison to the US, state regulations are restricted, but the member states of the EU have much more freedom and regulation over environmental policies. With regards to GM crops, most of the complaints about regulation have been placed at a national level, and these member states have demanded to be noticed by the government. Citizens have pressured them into raising health standards and have given many opportunities for smaller groups to place their concerns on the EU agenda. Additionally, member states are very dependent on each others choices under one market. Regulation is heavily dependent on each member states' policies. Because of this fragmentation of power, citizens must not only rely on the regulation opinions of their own member state, but also must rely on the competency of all the other memberstate representatves. Trust for the government would be very difficult to gain given the many regulatory failures that will be visited later. The EU is then coaxed into responding at the pleas of their citizens which in turns forces them to take on stricter regulations.

In summary, the government had slowly gained regulatory competence. Additionally, member state regulations over a dependent network has allowed for the improvement of stricter regulation in Europe overall.

Regulation failures in the past

The EU has approved more stringent policies over the years on the regulation of GMOs. There has been many cases of regulation failures that have undermined trust of administrative authorities to ensure the health of the citizens. Most notably, before the outbreak of Bovine Spongiform Encephalopathy (as known as mad cow disease), the European Union and the United states's regulations on the GM products were very similar.[86] This outbreak revealed the vulnerabilities of the EU's food safety regulation policies. Even though mad-cow disease was discovered in cows in the UK, the EC believed that it was not a threat on the safety of their European citizens. After conducting laboratory tests in the past, it showed evidence that BSE was transferable once consumed. This was just after the outbreak in the late 1980s, so the citizens were very wary of the health dangers, but the EC failed to place restrictions on the selling of beef. An outbreak of the disease occurred in the late 1990s resulting in many deaths. After analysis, it revealed that these cases were directly linked to the consumption of contaminated beef. In response, the EC finally banned export of beef and required the slaughter of all farm-cattle.[87]

[86] Paarlberg
[87] CBS News

Failure to recognize the contaminated beef was openly for sale had heavily caused the public to grow mistrust for the EU's regulatory policies on food safety. This was compounded with the commercialization of GM crops at the time. GM foods were only arriving at the doorsteps of Europe only to be shot down because of regulatory failures of the past. After this crisis, surveys were done in UK on the public opinion of GM foods. These surveys revealed that during the mad-cow disease outbreak, British citizens against GM foods rose from 25% to 40%.[88] Despite being a UK crisis, the member states also grew distrustful to any new technology in the food supply industry. Individuals became cautious of the government and any scientists that reassured their safety[89]. A prominent food sociologist claimed that madcow disease "was a water-shed for the food industry in [Europe]…For the first time people realized that merely attempting to ensure a culinary end product was safe to eat was not a good enough approach. We had to look at the entire process by which food is produced."[90]

This BSE regulatory failure had notable political implications all across Europe. First it led to the creation of the EFSA in 2000, increased the role of the Directorate General in regulation of the food and consumption, and member states also created subdivisions in food safety agencies.

As a comparison to the US, the US has not experienced the same regulatory failures like that of Europe. Even though there was events such as the Exon-Valdez oil

[88] Jordan
[89] 89.
[90] Williams

spill in 1989, this has not shown a direct breach on the the health of Americans. Generally the US has not had any regulation failures like that of Europe. Even with the occasional periodic food safety scares, they have generally been shortlived considering their impact on American socierty.

4.3 The complications that arise from policy worldwide

Even though there is general disagreement among US and the EU, other parts of the world can also feel these effects. The majority of GM crops are produced in 6 countries: USA, Argentina, India, Canada, and China.[91] Many other countries generally stay GM-free even if the countries has legal regulations allowing GM use and growth.[92] This inclination to stay GM-free is most likely due to bio-safety reasons, but it might also be because the country wants to have larger access to the world market. They would lose potential key import markets just because they grew GM.

Another issue that has come up is the concern over the contamination of nonGMO with GMO foods. This relates back to the Starlink corn fiasco where the corn was only approved for animal-feed purposes. The corn was exported and mixed with corn for human use lining some grocery stores and even entering many restaurants all over the country. Because of this, all farmers were heavily affected since their export sales had suffered[93]. If the United States is able to have this occur in their well-managed

[91] GMO Literacy Project
[92] Baumuller
[93] Bratsbies

networks, then it could be likely that GMO contamination could occur in developing countries that do not have as well structured regulation networks. With Europe's strict regulations and labeling guidelines (where 0.9% GM material is a GMO), it makes sense that many countries all over the world would have incentive to not use or grow GMOs.

Part 5 Conclusion

Scientists have claimed that that GMOs are safe to eat as their conventional counterparts. Under environmental risk review, GMOs reduce soil tillage, reduce pesticide use, and also reduce carbon emissions. Even though there is fear of pesticidal resistance, there have been governmental implementations in order to deter this. Despite with scientific consensus that GM crops are generally safe, two regions America and Europe have had differing views on GM. Europeans generally feel antagonistic toward GM foods while Americans generally are more welcoming. Lastly, in order to conclude the analysis a study on the governmental regulation was done and compared with their history of regulation. This reveals that with a increasing competency in regulation and many past regulation failures in the past, the European citizen was able to voice their concerns on the governmental agenda with more ease and after the BSE outbreak, citizens were shook and were generally mistrustful of their own government. The individual member states of the EU pressured the government in taking a better stance on regulation.

In conclusion, with all these disagreements between two countries, there are downstream effects of GM regulation on neighboring developing nations. This can have potential implications of GM use for the future. If individuals continue to prevent the proliferation of this technology, then scientists are unable to improve the safety of it. By halting GM production all together would disrupt the world's food supply and for any

developing nation, that desires to produce GM crops, would have to evaluate the potential market they could enter. But generally, how GM crops will be regulated over many world markets is still not for certain. Any country that is unable to guarantee the proper separation of GM and nonGM crops should potentially develop better measures in order to regulate.

Biography

Kathy Cao is a double major in Plan II Honors and Human Biology. She attended UT on the basis of obtaining a premedical education. She received the STEM Scholarship and President's Scholarship Award upon entering the University of Texas at Austin, and it has immensely helped her explore her education. She also was able to receive the Mitsubishi Study abroad scholarship so she could go to Japan after learning Japanese for 3 years.

One of Kathy's most memorable moments in her undergraduate career was with her new found love of fashion. Kathy was the officer at the Japanese Street Fashion Club at UT. She participates in the active community online, wears her quirky fashion everyday, and likes to delve in the economics behind the collectible quality of it. Even though she decided to become a premedical major, she would like to always hold her hobbies close. Kathy enjoys art, sewing, and keeping up with my J-fashion hobby. In the future, she hopes to continue embracing "avant-garde" fashion and possibly have enough free time to continue her art hobbies. @nyakokat on Instagram!

Annotated Bibliography

1. **FAS (2016). Genetically Modified crops: AGRICULTURAL BIOTECHNOLOGY: SAFETY, SECURITY, AND ETHICAL DIMENSIONS GENETICALLY MODIFIED CROPS.**
   This study shows data worldwide on the usage of GM crops. It also shows statistics on which countries exhibit GM crop acceptance and what crops are generally accepted.

2. **EPA. (2017, January 05). Modernizing the Regulatory System for Biotechnology Products. Retrieved May 07, 2017, from https://www.epa.gov/regulation-biotechnology-under-tsca-and-fifra/modernizing-regulatory-system-biotechnology-products**
   This reports the aftereffects of studies on GMO. GMO generation and crop yield, particularly the fundamental authoritative directions that it is headed. It also delves into issues on the educational scope of novel organic advances.

3. **FDA. (1994, May 18) Biotechnology of Food, FDA Backgrounder BG94-4, (Washington DC: Center for Food Safety and Applied Nutrition)**
   This FDA report explains about APHIS and how moving GM crops and other various agricultural goods can be done with more ease. This is significant for the paper because it shows how regulation is done in America with much more leniency compare to the EU where there are strict regulations on trans-country travel.

4. **See 54.**

5. **Brickman R., Jasanoff S., and Thomas I., (1985). Controlling Chemicals: The Politics of Regulation in Europe and the United States, Ithaca: Cornell University Press, 1985 and Graham Wilson , The Politics of Safety and Health Oxford: Clarendon Press**
   This paper explains the politics of risk regulation between Europe and US. This shows how regulation between the two have gone two very dichotomous ways. Environmental assessment in Europe shows much more stringent rules while the US has regulations with leniency. There are still similarities between the two so the discrepancy lies in how regulation failures are much more likely to occur in Europe compared to America

6. **See 56**

7. **Eichenwald k., Kolata m., and Petersen j., "Biotechnology Food: From the Lab to a Debacle." New York Times, January 25, 2001.**
   The regulation organizations heavily worked together with the industry were extremely supportive of technological innovation

8. **Juma, Calestous or Paarlberg, Robert L. (2015). The United States of Excess: Gluttony and the Dark Side of American.**
   As a comparison to Europe, America is generally an over-glutinous consumer. They have higher rates of obesity. This book was important for the study because I could further make these comparisons on culture.

9. **See 8**

10. **Nuffield Council on Bioethics. The Use of Genetically Modified Crops in Developing Countries. June 7, 2003. Available from http://www.nuffieldbioethics.org/publications/pp_0000000017.asp**
    This article looks into how genetically modified crops could potentially affect developing countries. It visits the benefits of GMOs and how they could provide for the populace.

11. **Maghari, B. M., & Ardekani, A. M. (2011). Genetically Modified Foods and Social Concerns. Retrieved May 07, 2017, from https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3558185/**
    This article looks into the populace's perceived risks about GM foods. It also explains the general concerns of the public like the comments about the environmental effects such as Bt-resistance in insects and provides many different examples that can be used in the biological methods of production section

12. **Jank, B., Gaugitsch H,. (2001) Assessing the Environmental Impacts of Transgenic Plants. Trends in Biotechnology**
    This article looks at the all the potential environmental impacts of GM crops. This includes escape into the environment, commingling with native counterparts and how this could reduce the biodiversity of a species.

13. **Séralini, Gilles-Eric, Emilie Clair, Robin Mesnage, Steeve Gress, Nicolas Defarge, Manuela Malatesta, Didier Hennequin, and Joël Spiroux De Vendômois. (2014) Republished Study: Long-term Toxicity of a Roundup Herbicide and a Roundup-tolerant genetically Modified Maize. Environ Sci Eur Environmental Sciences Europe 26.1 : n. pag. Web.**
    Monsanto study (2012) European study found that when rats fed a lifetime diet of genetically modified corn, resistant to the herbicide Roundup, had developed tumors. Rats died prematurely compared to the control group with a regular diet. There was a republication of Monsanto study which provokes the general public.The European Food Safety Authority declared that the study did not have sufficient scientific backing to be considered valid in risk assessment. The rats

that researchers chose were criticized to be prone to getting breast tumors. The corn was contaminated by a common fungus that causes hormone imbalance. The study didn't screen for many factors.

14. **Bruce T,. "Production of Therapeutic Proteins in Plants" (PDF). UNIVERSITY OF CALIFORNIA Division of Agriculture and Natural Resources.**
    This article visits the many possible creations with GM crops. They are not just for human consumption but can be used for many other beneficial things.

15. **Boerboom, C., Owen, M. (2007) National Glyphosate Stewardship Forum II: A Call to Action. St Louis, Missouri, p. 46**
    This book visits the way in which Bt-toxins can be implemented into the crop. Whole genome alignment is done with plants that have and do not have the gene to pinpoint the regions of difference

16. **Thorneycroft, D., Sherson, S. M., & Smith, S. M. (2001, August 01). Using gene knockouts to investigate plant metabolism. Retrieved May 07, 2017, from https://academic.oup.com/jxb/article/52/361/1593/538328/Using-gene-knockouts-to-investigate-plant**
    Gene knockouts on the plant can be used as a form of genetic engineering technique. These techniques are useful in finding the exact gene on the genome that controls for a selected trait such as plant metabolism
17. **Boyle, R., How To Genetically Modify a Seed, Step By Step. (n.d.). http://www.popsci.com/science/article/2011-01/life-cycle-genetically-modified-seed**
    This goes in depth for how a GM crop is created it includes talks about how monsanto also creates GM seeds. The approval process is long and strenuous and one sees that there are lots of tedious steps required. Selection of the most favorable genes are performed and further propagated down subsequent generations

18. **Kharkwal, M. C., & Roy, D. (2004). A Century of Advances in Plant Breeding Methodologies. Plant Breeding, 17-48. doi:10.1007/978-94-007-1040-5_2**
    This gives a good comparison between all the different plant breeding techniques. It gives a very good explanation of the way bacteria from Agrobacterium tumefaciens is incorporated into host genomes.

19. **Slater, Adrian; Scott, Nigel; Fowler, Mark (2008). Plant Biotechnology: the genetic manipulation of plants (2 ed.). Oxford, New York, USA: Oxford University Press Inc. ISBN 978-0-19-928261-6.**
    This shows an article with all the newest forms of genetic engineering. It gives small descriptions about the methods such as the gene gun technique, the

electroporation, and of the bacterial infection method. Particles of gold are used in order to properly be stable in the cell.

20. **Barry, M., Andersson, H., & Singh, R. (2003). Gene Gun Technologies. Gene and Cell Therapy, 263-285. doi:10.1201/9780824758608.ch15**
This article explains gene guns in depth and how they can be potentially used in cell therapy. The method in which the metal particle is used is studied with cell cultures. Gold or tungsten can be used in this case to have pieces of the DNA/gene of interest. There are generally two ways in order to do a gene gun transfer. First the cell culture will generally have the seeds on them and then a gun that is shot at a gold film that has the genes on them. They accelerated with impact onto the cells and get potentially incorporated into the DNA of the plant.

21. **Beilmann, A., K. Albrecht, S. Shultze, G. Wanner, and U. M. Pfitzner. (1992). Activation of a truncated PR-1 promoter by endogenous enhancers in transgenic plants. Plant Mol. Biol. 18:65-78.**
This article visits how transgenes are made with markers, promoters, and specific designer genes. They also go into the process of how transgenes are implemented into host cells. Host cells must be checked if they have assumed the gene usually this is through marker sequences.

22. **See 18.**

23. **NEB Biolabs, New England. "CRISPR/Cas9 and Targeted Genome Editing: A New Era in Molecular Biology." Reagents For the Life Sciences Industry. N.p., n.d. Web. CRISPR/CAS9 gene editing tool study.**
This article explains the mechanism in which CRISPR can be implemented. This development of efficient and reliable ways to make precise, targeted changes to the genome of living cells is a long-standing goal for biomedical researchers.

24. **Phillips, P. C. (2008, November). Epistasis—the essential role of gene interactions in the structure and evolution of genetic systems. Retrieved May 07, 2017, from https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2689140/**
Genes are not solely regulating one thing but they may be regulating many processes in the organism. This furthers the argument about how transgenes inserted in the genome can have many other potential protein effects. Unknown proteins can also result so usually GM crops must be studied with care.

25. **Naranjo S., (2009, June). Impacts of Bt crops on non-target organisms and insecticide use patterns.**
Under the environmental assessment of GM crops, it shows how Bt crops can have a potential to affect other nontarget organism that were unintended. This can include beneficial insects, birds, or important soil microorganisms. Bt must be readily easily removable from the environment once the plant that has the gene dies.

26. **Yaqoob, A., Shahid, A. A., Samiullah, T. R., Rao, A. Q., Khan, M. A., Tahir, S.,Husnain, T. (2016, June). Risk assessment of Bt crops on the non-target plant-associated insects and soil organisms. Retrieved May 07, 2017, from https://www.ncbi.nlm.nih.gov/pubmed/26857894**
This is another study on the environmental assessment of Bt crops.

27. **Lazebnik, J., Arpaia, S., Baldacchino, F. et al. (2017). Effects of a genetically modified potato on a non-target aphid are outweighed by cultivar differences. J Pest Sci doi:10.1007/s10340-017-0831-6**
This studies the additional nontarget studies explained before.

28. **See 27.**

29. **Royal Society (2002 February). Genetically modified plants for food use and human health—an update.**
There have been claimed accounts of allergens related to GM crops. These allergen cases are extremely rare and generally do not pose a risk to public health.

30. **Roh, J. Y., Choi, J. Y., Li, M. S., Jin, B. R., & Je, Y. H. (2007, April). Bacillus thuringiensis as a specific, safe, and effective tool for insect pest control. Retrieved May 07, 2017, from https://www.ncbi.nlm.nih.gov/pubmed/18051264**
This article explains how Bt incorporated GM crops are generally safe and any studies that have shown negative effects on nontarget organisms are usually insignificant. This article also goes into depth about the general effectiveness of pest control.

31. **Niederhuber. (2015, August 10)Insecticidal Plants: The Tech and Safety of GM Bt Crops. Retrieved May 07, 2017, from http://sitn.hms.harvard.edu/flash/2015/insecticidal-plants/**
This article explains the risks associated with GM Bt-crops. It talks about the potential to develop insect resistant species.

32. **Xu, C. (2015, August 14). Nothing to Sneeze at: the Allergenicity of GMOs. Retrieved May 07, 2017, from http://sitn.hms.harvard.edu/flash/2015/allergies-and-gmos/**
This Harvard study looks at the Starlink corn fiasco that happened in 2000, A rare case of a customer having an allergy to the Cry9C protein caused public skepticism on the safety of GM crops. The FDA furthers their study and claims that it still poses no significant risk as many other individuals are still consuming it with no issues.

33. **JEFCA. (2016, November). Chemical risks and JECFA. Retrieved May 07, 2017, from http://www.fao.org/food/food-safety-quality/scientific-advice/jecfa/en/**
This delves into more of the risk regulation with allergens in GMOs. Aftermarket procedures are still in effect even if the GM crop is on the shelves. This explains why the FDA continued tests even after the GM crop was approved to be used as animal-feed and was generally safe for consumption. When public unrest shows up or if the populace is concerned usually the FDA or USDA can conduct additional aftermarket tests.

34. **Burks AW, Fuchs RL. (1995). Assessment of the endogenous allergens in glyphosate-tolerant and commercial soybean varieties. Journal of Allergy and Clinical Immunology 96, 1008–1010.**
This study also visits the potential allergens associated with soybeans. It's interesting that this study also mentions that allergies to soy can be removed with silencing techniques in GM.

35. **Ho MW, Cummins. (2009). J. New evidence links CaMV 35S promoter to HIV transcription. Microb Ecol Health Dis.21(3-4):172–174.**
This CaMV 35S promoter is generally used as a transgene in order to "infect" a GM crop to accept a transgene. Majority of the GM crops that we eat today have this gene in it. This has created a bout of fear concerning the potential horizontal gene transfer. This study explains how human and plants generally share a similar gene and this can promote for the upregulation or enhancement of HIV infection in a person. More studies must be performed on this because it does not show all the potential effects.

36. **A. S. Bawa., K. R. Anilakumar., J Food Sci Technol. (2013 December) Genetically modified foods: safety, risks and public concerns—a review. 50(6): 1035–1046. doi: 10.1007/s13197-012-0899-1**
This article is very useful in understanding the perceived risks. Many conclusions about public concerns can be drawn. It talks about how there should generally be no scare of the risks of GM crops as these are posed as insignificant.

37. **Katirae Layla., (2014 October). Review of "Complete Genes May Pass from Food to Human Blood"**
This article goes in an in depth analysis of the Complete Genes May Pass from Food to Human Blood theory. The study when read by me, I felt that the individual did not do a very efficient job of providing enough sample size. It did not even explain how long the "DNA" was digesting in the stomach for either. Katirae explains how this research paper was done poorly and it fails to address many questions as it completely goes against our knowledge of how blood cannot carry huge macromolecules. This would not be evolutionarily beneficial to our race if so.

38. **Robert S. Peabody Museum of Archaeology, Phillips Academy, Andover, Massachusetts. Photo.**
Thousands of years of selective breeding of maize uncovered by archaeologists

39. **David W. Schindler; John R. Vallentyne (2008). The Algal Bowl: Overfertilization of the World's Freshwaters and Estuaries. Edmonton, Alberta: University of Alberta Press.**
This is a case study of how conventional crop techniques can have detrimental effects on the environment. This study was needed in order to compare GM with artificially selected crops. When crops are given pesticide resistance genes, farmers are able to spray less pesticides in order to compensate or the amount of yield. In fact it is much more cost efficient.

40. **Reicosky, D. Nutrient Cycling in Agroecosystems (1997) 49: 273. doi:10.1023/A:1009766510274**
This paper explains how nutrients can be cycled in an ecosystem. In this case, it talks about how conventional crop techniques can affect an environment by increasing the CO2 emissions. These emissions are then added into atmosphere thereby contributing to global warming.

41. **Gilbert, N. (2013, May 01). Case studies: A hard look at GM crops. Nature. http://www.nature.com/news/case-studies-a-hard-look-at-gm-crops-1.12907**
This nature magazine evaluates the actual risks of GM crops on the environment. Pesticidal resistance in insects can be created with GM. These can be mitigated with the proper techniques with governmental regulation. In a connected study it shows how in the early times when Bt-corn was slowly becoming popular, 1970s. The crop was then not working as effectively thereby leading to more spraying of pesticides and then more detrimental effects to the environment.

42. **EPA. (2001, October 16). Biopesticides Registration Action Document - Bacillus thuringiensis Plant-Incorporated Protectants: Insect Resistance Management. Retrieved from https://www3.epa.gov/pesticides/chem_search/reg_actions/pip/bt_brad.htm**
As a good supplement to the before article 42) this article shows the government regulations on which they can control pest resistance. In this case, pest resistance is mitigated with crop rotation on a yearly basis and also planting right next to a conventional crop**.**

43. **Lukaszewski, A. (2004). Chromosome manipulation and crop improvement. In: Encyclopedia of Plant and Crop Science . New York: Marcel Dekker.**
Crop improvement no matter what technique is used can have detrimental effects on a population's gene pool.

44. **National Research Council; Environmental Effects of Transgenic Plants: The Scope and Adequacy of Regulation**

This NRC article explains the different environmental effects of transgenic plants. It also goes into depth about the governmental regulations especially that of APHIS. APHIS explains how there is a general acceptance toward regulation on interstate areas, but it also explains how there is significantly no difference between GM crops and their conventional counterparts.

45. **National Research Council; Comparison of environmental assessment of transgenic plants with assessment of other agricultural technologies**
    This NRC article explains the different environmental effects of transgenic plants, but it also explains how there is significantly no difference between GM crops and their conventional counterparts.

46. **USDA: Environmental Effects of Transgenic Plants: The Scope and Adequacy of Regulation.**
    The NASEM evaluates the potential environmental risks of transgenics crops. Although they that conclude transgenics plants are strictly regulated, field monitoring may be needed and reinforced.

47. **Ferdman, R. A. (2015, July 06). Why we're so scared of GMOs, according to someone who has studied them since the start, Washington Post Weekly Edition.**
    This was the interview done with the food agriculturalist from OSU that has been studying the populace's opinion for more than a decade. He has come to terms that the GMO scare is because of unfamiliarity on the subject**.**

48. **Swardson. (1999, April 05). Round 2 of the Food Flight: Genetically Altered Items, Washington Post National Weekly Edition.**
    Swardson explains that western European countries share a generalized sentiment against food tampering. More people are moving away from modified foods including transgenic crops.

49. **Statista. (2016). United States and Europe Fast Food Establishments in 2016. In Statista.**
    This shows the graph of how the United States has much more fast food restaurants comparatively to Europe.

50. **Greenberg, D. (1999, July 07). The right to know what we eat, Washington Post National Weekly Edition**
    Greenburg explains that the controversy surrounding GMOs in the Unites states more of a political issue rather than a scientific one, and how producers are against regulations because of costs. At the expense of the customer, producers have been excluding information on production methods.

51. **Quinn., Young., (2015 April 14)., Why The FDA Has Never Looked At Some Of The Additives In Our Food. NPR.**
This article shows how there are loopholes in the system of additive approval.

52. **Vogel, D. (2012). Politics of precaution regulating health,safety and environmental risks in Europe and the US.**
Vogel writes a comprehensive analysis on the shift towards more stringent regulation of environmental pollution in Europe.

53. **Ottawa. (1999, May 01). Sticky labels. Retrieved May 07, 2017, from http://www.economist.com/node/321496**
This article visits the study on how culture plays a role in the perception of GMO labels on goods in the US and Britain. Britians see the GMO label as an additional consumer option. Americans see the GMO as a way to short the consumer.

54. **Lynch, D., Vogel, D. (2001, April 02). The Regulation of GMOs in Europe and the United States: A Case-Study of Contemporary European Regulatory Politics. Council on Foreign Relations Press.**
This article focuses on the differences of European and American regulation due to the differences in history and mostly focuses on risk regulation.

55. **MacKenzie, D. (1996, December 07). Vol. 152:2059, p5 Europe agrees on novel food labels.**
Reports on the compromise reached by the European Parliament and the 15 European Union (EU) countries concerning the labelling of genetically engineered soya beans. Features of the new arrangements; Other rules of EU states on the labelling of novel foods; Impact of genetic engineering on foods.

56. **Greenberg, D. (1999, July 07). The right to know what we eat, Washington Post National Weekly Edition,**
This article focuses on the populace's opinion on how they require labelling on all GM food products**.**

57. **Randall, J. (2008, August 12). Prince Charles warns GM crops risk causing the biggest-ever environmental disaster. Retrieved May 07, 2017, from http://www.telegraph.co.uk/news/earth/earthnews/3349308/Prince-Charles-warns-GM-crops-risk-causing-the-biggest-ever-environmental-disaster.html**
Head figures like Prince Charles proposed that GM crops can pose a detrimental risk on the environmental as well as

58. **Roseboro, K. (2004). Genetically altered foods and your health. North Bergen, NJ: Basic Health Publications.**
Roseboro argues for organic alternatives in place of GMOs, and considers

genetic engineering is a risky technology.

59. **Urry M., Parker. G., (1998). Enforcer to Monitor GM Crops: Farming Cunningham Heads Committee to Monitor Tests on Frankenstein Foods. *Financial Times***
This articles explains how leaders like Farming Cunningham have influenced the strict regulation of transgenics farming in Europe.

60. **Hoban T. (1997). Consumer Acceptance of Biotechnology: An International Perspective. *Nature Biotechnology.***
This explains how biotechnology is being accepted in a global setting. The benefits of genetic engineering has allowed it to permeate into many markets. Although GMOs have faced opposition, its prominent presence indicates that it is here to stay.

61. **Ayers T. (1998). A Tomato by Any Other Name? U.S. and EC Grapple with Labeling. Science**
This paper explores the effects of genetically engineered products as intellectual property and the resulting labeling of the products of this technology.

62. **Center for Food Safety. (2015). U.S. Polls on GE Food Labelling. Retrieved May 07, 2017, from http://www.centerforfoodsafety.org/issues/976/ge-food-labeling/us-polls-on-ge-food-labeling#**
Majority of Americans surprisingly desire their food to be labeled. It is regardless of what political party they stand in. This is focused on the idea that

63. **Caplan, A. (2015, September 08). GMO Foods Should be Labeled, But Not for Safety: Bioethicist. Retrieved May 07, 2017, from http://www.nbcnews.com/health/health-news/why-gmo-foods-should-be-labeled-n423451**
This is an article written by a proGM journalist. He claims that GM labels are not always bad because they could actual potentially help the argument that GM is safe. By labelling we can prove to antiGM individuals that after eating these Gm labelled foods for decades on end, nothing will happen.

64. **Breyer D, Herman P, Brandenburger A, Gheysen G., Remaut E, Soulmillion P, Van Doorsselaere J, Custers R, Pauwels K, Sneyers M (2009). Genetic modification through oligonucleotide-mediated mutagenesis. A GMO regulatory challenge? Environment Biosafety PMID:19833073; http://dx.doi.org/10.1051/ebr/2009007**
The EU generally has different ways of regulating GMOs where a 0.9% GM material organism or food product is a GM. The approach of regulating GM

products is contested with a new technique and this is the oligonucleotide-mediated mutagenesis.

65. **European Commission. (2007). 50 years of Food Safety in the European Union.**
This website shows the EC's history in its regulations.

66. **WHO. (2002). 20 questions on genetically modified foods. http://www.who.int/foodsafety/publications/biotech/20questions/en/index.html**
This article shows the most common questions about GM crops. It answers some precise definitions of what biotechnology and GMOs are

67. **FDA. Food and Drug Administration. (1992, May 29). Statement of Policy: Foods Derived from New Plant Varieties. http://vm.cfsan.fda.gov/~lrd/fr92529b.html**
This article from the FDA provides the definitions and labels that are important in defining what are GM crops are.

68. **See 2**

69. **Center for Food Safety. (2015). International Labeling Laws. Retrieved May 07, 2017, from http://www.centerforfoodsafety.org/issues/976/ge-food-labeling/international-labeling-law**
This CFS study shows how many countries require labelling and what this could mean for developing countries. Majority of countries require labelling of GM crops and products. This is useful as it also shows the dates in which approval was granted and the general populace's votes and opinions of them

70. **Public Law XII. (2016). Obama Administration.**
This public law implemented by obama illustrated how GM labels were desired by the populace. Individuals always had the right to know.

71. **Strom, S. (2015, December 02). Food Companies to Add Scan Codes With More Product Details. New York Times.Retrieved May 07, 2017, from https://www.nytimes.com/2015/12/03/business/food-companies-to-add-scan-codes-with-more-product-details.html**
This article shows the new implementation of Obama's law about mandatory GM labelling. Labels come in many forms and in this case they are scannable codes to let the consumer know. This can also show how there are more measures in which companies may take in order to get their food products approved. This would generally involve a longer and tedious process for approval of the food product.

72. **Food and Drug Administration. (1992, May 29). Statement of Policy: Foods Derived from New Plant Varieties.**
http://vm.cfsan.fda.gov/~lrd/fr92529b.html
The FDA generally has many laws based on the GM crops and they are generally regulated from a products-approach.

73. **See 72**

74. **International Food Safety Network (2001, March 11). Substantial Equivalence in Food Safety Assessment. Council for Biotechnology Information**
This article talks about the principle of substantial equivalence. This is important in assessing food safety risks especially in US. Despite this other countries also use this same principle but in different ways. In this case the EU uses it in the scientific assessment but still generate through a process approach of regulation in order to approve crops.

75. **Library of Congress. (2015). Restrictions on Genetically Modified Organisms: United States. Retrieved from**
http://www.loc.gov/law/help/restrictions-on-gmos/usa.php
This article shows the different restrictions on the moving and exportation of GM crops. GM crops can not always be freely distributed in the wild or on farmland without prior premarket approval by individuals involved in the Coordinated Framework.

76. **EPA. (2016, October 20). Regulation of Biotechnology for Use in Pest Management. from**
https://www.epa.gov/regulation-biotechnology-under-tsca-and-fifra/epas-regulation-biotechnology-use-pest-management
The EPA uses a approach for pest management in this cause this is done through crop rotations and planting GM crops right next to conventional counterparts.

77. **Tutelyan, V. (2013). Genetically modified food sources: safety assessment and control. London: Elsevier. p. 202**
This study shows how GM food sources must be regulated and there is a general scare that GM crops can contaminate conventional counterparts.

78. **U.S. Environmental Protection Agency. (2010). Cry1Ab and Cry1F Bacillus thuringiensis (Bt) Corn Plant-Incorporated Protectants.**
http://www.epa.gov/oppbppd1/biopesticides/pips/cry1f-cry1ab-brad.pdf

Bt-crops are generally regulated with care by the USDA, in this case they first check if the crop will have detrimental effects on nontarget organisms and see if there are ways in order to deter resistance in pests. The approval process for GM crops can also be found on this page. Cry9c proteins cause the deterrence of lepidoptera on plants, but generally superbugs can be created with this, and potentially species like butterflies can be affected.

79. **EFSA. (2016). Genetically Modified Organisms. Retrieved from http://www.efsa.europa.eu/en/topics/topic/genetically-modified-organisms**
    The EFSA is the scientific inquiry part of regulation. It was created to provide the necessary evidence for regulatory agencies like the EC and member states of the EU to properly regulate GM crops.

80. **Davidson J., (2010). GM plants: Science, politics and EC regulations. Plant Science. 178 (2): 94–8. doi:10.1016/j.plantsci**
    This article talks about the GM plants and gives a good general explanation on how they are regulated. It also provides a good example of the

81. **European Commission. GMO Legislation. Retrieved from https://ec.europa.eu/food/plant/gmo/legislation_en**
    This web page shows all the past regulations on GM crops and has further updates. GM stacks are GM organisms that have more than one transgene associated with them and the EC claims that they need not be regulated any different than their one transgene counterparts. This is an interesting statement because the GM crops are generally said to be regulated by a process approach for the EU and they generally believe that GM crops are different from traditional counterparts--artificially selected. The definitions can be retrieved from this and this is useful for the comparison with American politics. The different regulation agencies and all the relevant articles in which they regulate GM approval can be found on this website.

82. **See 80**
83. **See 55**
84. **See 55**

85. **Alison Maitland, "European News Digest: Call for Ban on Biotech Beans," Financial Times, October 8, 1996: 2.**
    This article shows the general publics' view on GM crops. Public outcry against approving GM crops have been heavily important. It also has a few polls and survey data useful for the analysis.

86. **Paarlberg, Robert L. (2016) "The Contested Governance of GM Foods: Implications for USEU Trade and the Developing World." Weatherhead Center for International Affairs Working Paper Series. Paper No. 02-04. Cambridge, MA. pg 24.**

Compares how conventional counterparts are similar to GMOs. Also further analyzes how the EU responded in the BSE scare in 1996. This have heavily affected the market place for further accepting GM foods. Europeans were originally accepting of GM counterparts and saw the food as safe, but over time they were not able to confirm this.

87. **CBS News. (2006, October 26). http://www.cbsnews.com/news/chronology-of-mad-cow-crisis/**
This article on CBS shows the chronology of the BSE crisis and how Europe dealt with it. It also shows how this has detrimental effects on their economy. The effects of BSE have been all but detrimental for Europe. It further continued in France and Germany which instigated a huge outcry against the government regulators who did not properly deal with the situation. The BSE individuals

88. **Jordan A., (2012). Environmental Policy in the European Union: Actors, Institutions, and Processes. Print. P. 236**
This article visits the very many environmental policies that the EU faces when evaluating risk to the environment and risk to the health of individuals. The many regulatory bodies are illustrated in this article and their different powers that are associated with regulation DXIII has the most power much more than the EPA in the US. The processes in which EU approves of products is based on the process approach.

89. **Williams N., (2001, March). Europe opens the door to GM crops. Volume 11, Issue 6, pR199–R200, DOI: http://dx.doi.org/10.1016/S0960-9822(01)00102-6**
This magazine reviews how there are only a few GM crops that are accepted in the European Union. It also visits the history on how the European Union had difficulties with approving given the different opinions of the member states.

90. **See 89.**

91. **GMO Literacy Project. (2016). Where are GMOs grown and banned? Retrieved May 07, 2017, from https://gmo.geneticliteracyproject.org/FAQ/where-are-gmos-grown-and-banned**
This article shows how GMOs are grown mainly in 6 different countries. The specific GM crops that the US exports are mainly soybean and corn. They are generally banned in many others. All countries are

92. **Baumuller, H. (2003, August). Domestic Import Regulations for Genetically Modified Organisms and their Compatibility with WTO Rules. International Centre for Trade and Sustainable Development.**
This article reviews the import regulations for GMs and showed how there are general discrepancies between two countries. Different countries have different labels so this creates conflicts as one attempts to export them to other countries.